

rejected on grounds of obviousness-type double patenting.

As indicated to the Examiner, there are a number of structural differences between the catheter shown in Csapo and the catheter of the present invention, including the claimed combination of elements which protect the thermistor and enhance the overall integrity of the catheter, and the central positioning of the thermistor within the right ventricle of the heart. Although Csapo's catheter is structurally similar to the presently claimed catheter, the structural elements referenced above are critical to successful long-term performance of the catheter in an exercise responsive pacemaker and, therefore, the combination of elements recited in independent claim 10, as now amended, is believed unobvious over Csapo.

Csapo uses only single-wire leads to a thermistor and does not disclose any method for protecting the thermistor or its leads from the flexing that occurs in the catheter due to movement within the heart. Instead, Csapo states that the lead cables and electrodes require highly flexible materials. Some flexibility in the catheter is desirable, but not at the interfaces between the thermistor and its leads and between the thermistor leads and any external wires joining the thermistor to the pacemaker. Indeed, in these areas it is critical to maintain rigidity to adequately protect the thermistor from catheter flexure caused by heart movement. For this reason, the thermistor of the presently claimed combination and its leads are encased in epoxy and received in the lumen of a tubing portion which is at

least partially filled with an elastomer to prevent relative movement. The thermistor leads are terminated in two rigid conductive tubing sections soldered to bifilar wound coil wires for electrical connection to the pacemaker. The rigid tubing sections provide strain relief between the bifilar wires and the thermistor leads, and the overall structure around the thermistor protects the thermistor from breakage due to flexure. The epoxy around the thermistor serves a second purpose: It reduces the migration of ions from the blood into the thermistor, which ions have been found to cause substantial drift in the resistance of an implanted thermistor. In the preferred embodiment, ion migration effects have been further reduced by the use of a suitable thermistor such as Penwall Electronics type GA51J1, a glass bead thermistor.

Another important aspect of the present invention is the mounting of the thermistor inside the catheter in a location where it will be centrally positioned within the right ventricle of the heart when the catheter is implanted. The optimum location for a pacing electrode is in the apex of the ventricle, in which area the pacing electrode rests in the trabeculae of the myocardium. A catheter-based sensor with a thermistor mounted at the distal tip of the catheter immediately adjacent to a pacing electrode, such as that shown by Csapo, cannot provide accurate measurements of central venous blood temperature because of insufficient blood flow through the trabeculae in the apex of the ventricle. Instead, such a sensor would simply measure the temperature of the apical

myocardium. Tissue growth around the catheter tip only compounds the problem by further inhibiting the flow of blood around the thermistor.

Csapo clearly had the motivation to place a temperature sensor in a proper location to measure central blood temperature. One of the stated aims of his invention was to use that temperature for control of pacemaker frequency. Nevertheless, he chose to position the thermistor at the distal tip of the catheter, where accurate measurement of central blood temperature is impossible. In view of Csapo's motivation to position the thermistor properly, his failure to appreciate the significance of centrally positioning the thermistor in the ventricle is evidence that the presently claimed combination is not obvious.

Central positioning of the thermistor, and the structure protecting the thermistor, are critical to the successful long-term use of a catheter-based temperature sensor in cardiac care. The combination of these elements and the other elements claimed in amended claim 10, taken as a whole, are believed to be unobvious over Csapo and all prior art of record.

Applicants recognize, as discussed with the Examiner, that bifilar wire is known for use in pacemaker leads, as illustrated by U.S. Patent No. 4,399,820 to Wirtzfeld et al. Wirtzfeld et al. disclose an optoelectronic measuring probe in a stimulation catheter for the control of pacemaker stimulation frequency as a function of central venous blood oxygen saturation. This patent further discloses adhesive bonding of LEDs and

phototransistors to metallic annular elements in the measuring probe, adhesive bonding of an insulator between the metallic annular elements, and welding of a glass ring to the annular elements for protection of the LEDs and phototransistors. However relevant these teachings may be to optical measurement of blood oxygen saturation, they appear to be only marginally relevant to applicants' unique combination of elements claimed in amended claim 10 and the claims depending therefrom, including the combined use of epoxy, elastomer and rigid conductive tubing sections joining a pair of bifilar coil wires to thermistor leads to maintain structural integrity of a temperature sensor for use in an exercise responsive pacemaker, and the central positioning of a thermistor in the right ventricle of a heart to obtain an accurate temperature measurement.

Regarding the double-patenting rejections of claims 15 and 16, the CCPA indicated in In re Vogel, 164 U.S.P.Q. 619 (CCPA 1970), cited in the M.P.E.P. with respect to double patenting, that "same invention" means identical subject matter. A copy of the cited case is enclosed herewith for the convenience of the Examiner. An invention defined by one claim is not the same as that defined by a second claim where the former claim is broader than the latter. "A good test, and probably the only objective test, for 'same invention,' is whether one of the claims could be literally infringed without literally infringing the other. If it could be, the claims do not define identically the same invention." In re Vogel at 622.

Claim 1 of applicants' U.S. Patent No. 4,436,092 could be literally infringed by many cardiac pacemakers which would not infringe claim 15 (or 16) of the application. Any temperature-sensing pacemaker which does not have means for calculating the derivative of a sensed body temperature ( $dT/dt$ ) would not literally infringe claim 15, but could literally infringe claim 1 of the patent. For example, a pacemaker might implement an algorithm by which it senses temperature and changes heart rate when the sensed temperature exceeds a certain threshold, or an algorithm by which heart rate changes linearly with temperature. A pacemaker with a means for implementing one of these algorithms could infringe claim 1 of the patent, assuming all other claimed elements were present, without infringing claim 15 of the present application. Therefore, the inventions of claim 15 and 16 are not the same as the invention defined by claim 1 of the patent.

While the scope of claims 15 and 16 is not identical with that of patent claim 1, the variations between them are considered sufficiently small that a terminal disclaimer may be required in order to place these claims in condition for immediate allowance. Accordingly, a terminal disclaimer is being filed herewith. This terminal disclaimer is also believed to obviate the rejections of claims 17 and 18 on grounds of double patenting.

Claim 13 has been amended to make it depend from independent claim 10, consistent with the cancellation of claims 11 and 12. Claim 14 has been amended to delete the reference to a thermistor, consistent with the addition of the reference to a thermistor in amended claim 10.

In view of the foregoing remarks and amending changes, independent claims 10 and 15, and claims 13-14 and 16-18 respectively depending therefrom, are believed to be in condition for immediate allowance. Allowance by the Examiner of all 7 pending claims is respectfully requested.

Respectfully submitted,

By William F. Bahret  
William F. Bahret  
Reg. No. 31,087  
Woodard, Weikart, Emhardt  
& Naughton  
One Indiana Square, Suite 2600  
Indianapolis, Indiana 46204  
  
(317) 634-3456

Enclosure